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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,814	06/29/2001	Jiangchun Xu	210121.427C26	7420

500 7590 10/10/2006

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/895,814	XU ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *18 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *18 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *December 2, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Response to 312 amendmen, Petition Approvalt.

1. It is noted that Notice of Withdrawal from Issue was mailed to Applicant on September 8, 2006 because upon review and reconsideration of the IDS submitted on December 2, 2004, wherein Examiner inadvertently omitted consideration of US Patent 6,329,505 and US Patent No. 5,786,148, it was found that prior art that should have been cited in the prosecution of the case was inadvertently omitted.

2. The amendment under 35 CFR 312 filed June 6, 2005, in response to the Office Action mailed March 4, 2005, and the Petition filed June 6, 2005 are acknowledged and have been entered. Claims 18 and 20-23 are now pending and under consideration.

3. Applicant's recitation of the priority date for sequence 160-174 of SEQ ID NO:525 as June 13, 2000, for sequences 110-124, 125-139, 135-149, as June 27, 2000 and for sequence 155-170 as February 9, 2001 in the paper filed June 6, 2005 is acknowledged.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 18 and 20-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,465,611, priority date 9/23/1998.

The claims are drawn to a method for stimulating and/or expanding T-cells comprising contacting T-cells *in vitro*, with at least an immunogenic fragment of the polypeptide consisting of SEQ ID NO:525, to permit stimulation and/or expansion of T-cells specific for SEQ ID NO:525, wherein said immunogenic fragments are amino acids 110-124, 125-139, 135-149, 155-170, 160-174.

US Patent 6,465,611 claims "An isolated polypeptide effective for eliciting a human T-cell response, said polypeptide having at least 95% identity to the entirety of SEQ ID NO: 327 and comprising no more than 220 amino acid residues, said polypeptide being present in a formulation comprising a physiologically acceptable carrier and an adjuvant. (claim 6), wherein SEQ ID NO:327 is 100% identical to residues 35-254 of the instant SEQ ID NO:525 and therefore comprises all of the claimed "immunogenic fragments" and teaches that "The predominant method of procuring adequate numbers of T-cells for adoptive immunotherapy is to grow immune T-cells in vitro. Culture conditions for expanding single antigen-specific T-cells to several billion in number with retention of antigen recognition in vivo are well known in the art." The specification then provides teachings drawn to these well known methods. The specification further teaches that "The polypeptides disclosed herein may also be employed to generate and/or isolate tumor-reactive T-cells, which can then be administered to the patient." The specification further teaches that "Alternatively, peptides corresponding to immunogenic portions of the polypeptides may be employed to generate tumor reactive T cell subsets by selective in vitro stimulation and expansion of autologous T cells to provide antigen-specific T cells which may be subsequently

transferred to the patient as described, for example, by Chang et al, (Crit. Rev. Oncol. Hematol., 22(3), 213, 1996)."

Given that the instant reference claims an isolated polypeptide effective for eliciting a human T-cell response, said polypeptide having at least 95% identity to the entirety of SEQ ID NO: 327 and comprising no more than 220 amino acid residues, which clearly includes SEQ ID NO:327, given that SEQ ID NO:327 comprises at least all of the claimed immunogenic fragments of SEQ ID NO:525, given that the specification teaches that the polypeptides of the invention may be employed to generate tumor reactive T cell subsets by in vitro stimulation and expansion of autologous T cells, given that the specification teaches the conventional nature of the in vitro stimulation and/or expansion of T cells, one would immediately envision the instantly claimed method of stimulating and/or expanding T cells with SEQ ID NO:327 and all of the limitations of the claims are met.

7. Claims 18 and 20-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,329,505, priority date July 13, 1999.

The claims are drawn to a method for stimulating and/or expanding T-cells comprising contacting T-cells *in vitro*, with at least an immunogenic fragment of the polypeptide consisting of SEQ ID NO:525, to permit stimulation and/or expansion of T-cells specific for SEQ ID NO:525, wherein said immunogenic fragment is amino acids 110-124, 125-139, 135-149, 155-170, 160-174.

The specification teaches that the "present invention provides compositions and methods for the diagnosis and therapy of cancer, such as prostate cancer" comprising "at least an immunogenic portion of" SEQ ID NO:525. The specification further teaches that "the compositions described herein may be used

for immunotherapy of cancer, such as prostate cancer." And further teaches that "immunotherapy may be passive immunotherapy, in which treatment involves the delivery of agents with established tumor-immune reactivity (such as effector cells or antibodies) that can directly or indirectly mediate antitumor effects and does not necessarily depend on an intact host immune system. Examples of effector cells include T cells as discussed above, T lymphocytes (such as CD8.sup.+ cytotoxic T lymphocytes and CD4.sup.+ T-helper tumor-infiltrating lymphocytes)". In addition, the specification teaches that effector cells may generally be obtained in sufficient quantities for adoptive immunotherapy by growth in vitro as described in the specification wherein the stimulation and expansion of T-cells by contact with polypeptides of the invention is exemplified. The specification further teaches that culture conditions for expanding single antigen-specific effector cells to several billion in number with retention of antigen recognition in vivo are well known in the art."

Given that the instant reference teaches a polypeptide with 100% identity to SEQ ID NO:525, which clearly reads on all of the immunogenic fragments of SEQID NO:525 claimed, given that the specification teaches that the therapeutic compositions include at least an immunogenic portion of SEQ ID NO;525, given that the specification teaches that immunotherapy may be passive which includes the delivery of effector cells that are produced in vitro using the polypeptides of the invention, given the exemplification of T-cell stimulation and expansion using polypeptides of the invention, given that the specification teaches the conventional nature of the in vitro growing of/that is the stimulation and/or expansion of T cells, one would immediately envision the instantly claimed method of stimulating

and/or expanding T cells with SEQ ID NO:525 of the prior art reference and all of the limitations of the claims are met.

Claim Rejections - 35 USC § 112

New Grounds of Rejection

8. Claims 18, 20-23 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 18, 20-23 are drawn to a method for stimulating and/or expanding T-cells comprising contacting T-cells *in vitro*, with at least an immunogenic fragment of the polypeptide consisting of SEQ ID NO:525, to permit stimulation and/or expansion of T-cells specific for SEQ ID NO:525. It is noted that, given the limitation "at least an immunogenic fragment of SEQ ID NO:525" the claims in fact are read as drawn to immunogens that comprise immunogenic fragments of SEQ ID NO:525 but are not limited to contiguous resides of SEQ ID NO:525. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by

> function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product critical to the claimed invention, that is the "at least an immunogenic fragment of the polypeptide consisting of SEQ ID NO:525" itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the immunogen required for method for stimulating and/or expanding T-cells comprising contacting T-cells *in vitro*, per Lilly by structurally describing a representative number of immunogens with at least an immunogenic fragment of SEQ ID NO:525 by structurally describing a representative number of immunogens with at least an immunogenic fragment of SEQ ID NO:525 or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe immunogens with at least an immunogenic fragment of SEQ ID NO:525 required to practice the method of claim 1 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any immunogens with at least an immunogenic fragment of SEQ ID NO:525, nor does the specification provide any partial structure of such immunogens with at least an immunogenic fragment of SEQ ID NO:525, nor any physical or chemical characteristics of the

immunogen nor any functional characteristics coupled with a known or disclosed correlation between structure and function other than fragments consisting of contiguous amino acids of SEQ ID NO:525. Although the specification discloses these fragments, this does not provide a description of the immunogens with at least an immunogenic fragment of SEQ ID NO:525 that function as claimed that would satisfy the standard set out in Enzo.

The specification also fails to describe immunogens with at least an immunogenic fragment of SEQ ID NO:525 by the test set out in Lilly. The specification describes only polypeptide, SEQ ID NO:525 and fragments consisting of contiguous amino acids of SEQ ID NO:525. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of immunogens with at least an immunogenic fragment of SEQ ID NO:525 that is required to practice the claimed invention. Since the specification fails to adequately describe the broadly claimed immunogen, it also fails to adequately describe the claimed method. It is noted that the rejection can be obviated by amending the claims to recite, for example, "A method for stimulating and/or expanding T-cells comprising contacting T-cells *in vitro* with a fragment of the polypeptide consisting of SEQ ID NO:525 wherein the fragment is immunogenic, wherein said immunogenic fragment is.....".

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

(571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Ungar
Primary Patent Examiner
September 15, 2006

EXPRESS MAIL NO. EV530946025US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Jiangchun Xu et al.
Application No.	:	09/895,814
Filed	:	June 29, 2001
For	:	COMPOSITIONS AND METHODS FOR THE THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Examiner	:	Susan Ungar
Art Unit	:	1642
Docket No.	:	210121.427C26
Date	:	June 6, 2005

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.48(b)

Commissioner for Patents:

Applicants hereby request that the inventorship of the above-identified application be amended to delete Jiangchun Xu, Davin C. Dillon, Jennifer L. Mitcham, Susan L. Harlocker, Yuqiu Jiang, Gary R. Fanger, Marc W. Retter, John A. Stolk, Craig H. Day, Thomas S. Vedvick, Darrick Carter, Samuel X. Li, Aijun Wang, Yasir A. W. Skeiky, William Hepler, John Hural, Patricia D. McNeill, Raymond L. Houghton, Carlota Vinals y de Bassols. It is hereby acknowledged that the deleted inventors' invention is no longer being claimed in the above-identified application. The correct inventorship is as follows: Michael D. Kalos and Robert A. Henderson.

06/09/2005 MAHMED1 00000089 09895814
01 FC:1464 130.00 OP

The Petition for Correction of Inventorship dated June 6, 2005 is acknowledged and has been entered. Upon review and examination, the Petition for Correction of Inventorship is APPROVED.

Susan Ungar, PhD
Primary Patent Examiner
1642
571-272-0837

Response to Rule 312 Communication	Application No.	Applicant(s)	
	09/895,814	XU ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

1. ☒ The amendment filed on *June 6, 2006* under 37 CFR 1.312 has been considered, and has been:

   a) ☒ entered.

   b) ☒ entered as directed to matters of form not affecting the scope of the invention.

   c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
   Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

   d) ☐ disapproved. See explanation below.

   e) ☐ entered in part. See explanation below.

Susan Ungar
Primary Examiner
Art Unit: 1642